

### **REMARKS**

The present application is directed to compositions and methods involving therapeutic delivery compounds. The compounds are particularly suited for the effective delivery of genetic matter and other compounds to the interior of cells.

Following entry of this amendment, Claims 1, 22-23, 25, 27-31 and 37-40 will be pending. Claims 2-21, 24, 26, 32-36 and 41-42 have been cancelled without prejudice. Claim 37 is allowed and, as indicated by the Examiner in Box 6 of the Advisory Action mailed July 1, 2005, Claims 1, 23, 25, and 27-31 would be allowable if submitted in a separate timely filed amendment canceling the non-allowed claims. No new matter is added and support for the amendments is found throughout the specification.

#### ***Claim rejections under 35 U.S.C. § 112, second paragraph***

In the March 22, 2005 Office Action, the Examiner rejected Claim 32 under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants respectfully submit that Claim 32 has been cancelled herein and renders the Examiner's rejection moot. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

#### ***Claim rejections under 35 U.S.C. § 112, first paragraph***

The Examiner rejected Claims 1, 6, 7, 9, 14, 15, 18, 19, 21-25 27-36 and 38-42 under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement.

The Examiner stated that Claims 1, 6, 7, 9, 14, 15, 18, 19, 21-25 and 27-31 recite the limitation "the polyoxyethylene portion of the block copolymer is approximately 1% to approximately 45% of the total weight of the block copolymer." The Examiner concluded that there is no support for this limitation. Applicants respectfully traverse.

Block copolymers comprising a polyoxyethylene portion of approximately 1% to approximately 45% of the total weight of the block copolymer are disclosed on at least Table II (page 17) of the instant application. Table II discloses propriety copolymers that represent both the lower (CRL-8950 (~5%); CRL-1235 (~5%); CRL-1190 (~5%) CRL 336 (~5%)) and upper

range (CRL-85174 (~40%) of the polyoxyethylene portion of the block copolymer as claimed. In addition, applicants direct the Examiner to page 15, lines 30-34, of the present application where applicants state, “It should be understood that the molecular weight and percentage ranges that are described for the block copolymer are to be considered outside ranges and that any population of molecules that falls within the stated ranges is considered an embodiment of the present invention.” (emphasis added).

In an effort to facilitate prosecution, applicants have amended the claims to recite that the polyoxyethylene portion of the block copolymer is approximately 1% to approximately 50% of the total weight of the block copolymer. Applicants respectfully submit that, for at least the above reasons, they have overcome the Examiner’s rejection under §112, first paragraph, and request its withdrawal.

The Examiner also rejected Claims 32 and 33 for failing to comply with the written description requirement. The Examiner concluded that no copolymers of 750-1000 Daltons were provided. Applicants respectfully submit that Claims 32 and 33 have been cancelled herein and render the Examiner’s rejection moot. Accordingly, applicants request withdrawal of the Examiner’s rejection of Claims 32 and 33 under §112, first paragraph.

The Examiner rejected Claim 33 for failing to comply with the written description requirement on the basis that a block copolymer having a polyoxyethylene portion of “approximately 10%-30% of the total weight of the block copolymer” was not supported by written description. Applicants respectfully submit that Claim 33 has been cancelled herein and renders the Examiner’s rejection moot. Accordingly, applicants request withdrawal of the Examiner’s rejection under §112, first paragraph.

The Examiner also rejected Claims 34-36 for failing to comply with the written description requirement on the basis that a block copolymer having a polyoxypropylene portion “between approximately 4400 and 15,000 Daltons” was not supported by written description. Applicants respectfully submit that Claims 34-36 have been cancelled herein and render the Examiner’s rejection moot. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

The Examiner also rejected Claims 41 and 42 for failing to comply with the written description requirement on the basis that a block copolymer having a polyoxypropylene portion “between approximately 4740 and 15,000 Daltons” was not supported by written description. Applicants respectfully submit that Claims 41 and 42 have been cancelled herein and render the Examiner’s rejection moot. Accordingly, applicants request withdrawal of the Examiner’s rejection under §112, first paragraph.

***Claim rejections under 35 U.S.C. § 102***

In the Office Action mailed March 22, 2005, the Examiner rejected Claims 1-4, 9-12, and 19 as anticipated by Allison *et al.*, U.S. 5,376,369 (hereinafter “Allison *et al.*”) under 35 U.S.C. §102(b). The Examiner stated that Allison *et al.* teach that Pluronics L101, L121 and L122 could be used as adjuvants in the delivery of whole viruses *in vivo* as vaccines and that an expression vector capable of expressing the genes is anticipated by the viruses themselves, which are capable of expressing their own genes.

Applicants respectfully submit that Claim 1 has been amended to include the limitations of Claim 18, now cancelled, which the Examiner indicated was free of the prior art. Claims 2-4, 9-12 and 19 have also been cancelled. Accordingly, applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §102(b).

The Examiner rejected Claims 1-3, 9-11, 19 and 21 as being anticipated under 35 U.S.C. § 102(e) by Wasmoen *et al.*, U.S. 5,656,275 (hereinafter “Wasmoen *et al.*”) as evidenced by Osorio *et al.*, WO 99/39733 (hereinafter “Osorio *et al.*”). The Examiner stated that Wasmoen *et al.* teach that Pluronic L121 could be used as an adjuvant in the delivery of whole viruses *in vivo* as vaccines and that an expression vector capable of expressing genes is anticipated by viruses, which are capable of expressing their own genes.

Applicants respectfully submit that Claim 1 has been amended to include the limitations of Claim 18, now cancelled, which the Examiner indicated was free of the prior art. Claims 2-3, 9-11, 19 and 21 have also been cancelled. Accordingly, applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §102(e).

***Claim rejections under 35 U.S.C. § 103***

In the March 22, 2005 Office Action, the Examiner rejected Claims 1, 6, 7, 9, 14-15 and 34 as being unpatentable under 35 U.S.C. § 103(a) over Wasmoen *et al.* in view of Miyamura *et al.* U.S. 5,372,928 (hereinafter "Miyamura *et al.*"). The Examiner stated that Wasmoen *et al.* teach that Pluronic L121 could be used as an adjuvant in the delivery of whole viruses *in vivo* as vaccines and that whole viruses could be considered expression vectors.

Applicants respectfully submit that Claim 1 has been amended to include the limitations of Claim 18, now cancelled, which the Examiner indicated was free of the prior art. Claims 6, 7, 9, 14-15 and 34 have also been cancelled. Accordingly, Applicants respectfully request the withdrawal of the rejection of claims under 35 U.S.C. §103(a).


**CONCLUSION**

The foregoing is submitted as a full and complete Response to the Office Action mailed March 22, 2005 and the Advisory Action mailed September 14, 2005. For at least the reasons given above, applicants submit that the claims in the present application are in condition for allowance, and such action is courteously solicited.

No additional fees are believed due; however, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, to Deposit Account No. 11-0855.

The Examiner is invited and encouraged to contact the undersigned attorney of record at 404-745-2473 or the telephone number listed below, if such contact will facilitate an efficient examination and allowance of the application.

Respectfully submitted,

  
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